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DEC 20 2012

Certified
+ ISO 13485 & 14971
+ 9001 Compliant
+ WBE

ATTACHMENT 4

510(K) SUMMARY

This summary of the Special 510(k) information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR807.92.

510(k) Number: _____

4.1 APPLICANT INFORMATION

Date Prepared: November 5, 2012

Name and Address: Actuated Medical, Inc.
310 Rolling Ridge Drive
Bellefonte, PA 16823
Ph: 814-355-0003
Fax: 814-355-1532

Contact Person: Debora L. Demers, Ph.D., Director of QA/RA
Ph: 814-355-0003 x112
Fax: 814-355-1532
Email: debora.demers@actuatedmedical.com

4.2 DEVICE INFORMATION

Classification: KNT
Trade Name: TubeClear™
Common Name: In Patient Nasogastric Tube Clearing System
Classification Name: Tubes, Gastrointestinal and Accessories,
21 C.F.R. §876.5980

4.3 PREDICATE DEVICE

TubeClear, manufactured by Actuated Medical, Inc. (AMI) and cleared under 510(k) K121571, is the Predicate Device. TubeClear is composed of a reusable Control Box and single use Clearing Stem. One Control Box model, Model 101 is used to actuate all Clearing Stem models. TubeClear has two Clearing Stem models, Models NG-1036 and NG-1043.

4.4 PROPOSED DEVICE DESCRIPTION

The Proposed Device is TubeClear. TubeClear is composed of a reusable Control Box and single use Clearing Stem. One Control Box model, Model 101 is used to actuate all Clearing Stem models. TubeClear has two Clearing Stem models, Models NG-1036 and NG-1043.

The Operator manually inserts the Clearing Stem into the feeding or decompression tube (i.e., Tube) and directs the Clearing Stem's advancement along the inside of the Tube. The Control Box Motor via electromechanical actuation creates a linear reciprocating motion. The linear reciprocating motion is transferred to the proximal end of the Clearing Stem which contains a Wire that also reciprocates. Because the Wire is continuous throughout the Clearing Stem, the reciprocating motion is further transferred to the distal Tip of the Wire. The motion at the Wire Tip mechanically acts on the occlusion, breaks up the occlusion and restores Tube patency.

Because the Control Box remains outside of the patient and it functions only to provide actuation to the Clearing Stem when the two are attached, the Clearing Stem is considered to be the primary element of TubeClear.

4.5 INDICATIONS FOR USE

The Proposed Device and the Predicate Device, have the exact same indications for use. TubeClear is indicated for use only and solely in clearing occlusions / clogs in nasogastric (NG) tubes (i.e., tubes that are placed through the nose and reside in the stomach) of adult patients. Clearing Stem Model NG-1036 is indicated for use in nasogastric tubes that are of size 10 – 14 French and have a length of 36 – 42 inches (91 - 108 cm). Clearing Stem Model NG-1043 is indicated for use in nasogastric tubes that are of size 10 – 18 French and have a length of 43 - 50 inches (109 – 127 cm).

4.6 TECHNOLOGICAL CHARACTERISTICS

The Proposed Device and the Predicate Device, have the exact same design features with one exception. The Predicate Device has pad printed centimeter markings on a 45 cm (18 in) segment of the Clearing Stem and the Proposed Device has NO pad printed centimeter markings on the 45 cm (18 in) segment of the Clearing Stem.

4.7 RISK ANALYSIS

The risk analysis methods used to assess the safety and efficacy impact of the design modification were Preliminary Hazard Analysis (PHA) and Failure Modes and Effects Analysis (FMEA). The Design Requirements Document, Design Input Output Matrix, and Finished Product Specification were also reviewed.

It was determined that the removal of centimeter marks did not add any new safety risk to TubeClear. The presence of centimeter markings is not a design requirement.

It was determined that the previously conducted design verification activities were still applicable. The proposed design modification will not affect the following:

1. Operation and performance of the Control Box.
2. Performance of the Clearing Stem.
3. Shelf Life.
4. Biocompatibility.
5. Packaging and Transportation.
6. Software / Firmware.
7. Electromagnetic Compatibility / Electrical Safety.

4.8 NON-CLINICAL PERFORMANCE DATA

Bench Testing focused on Usability Testing to support Design Validation. Usability and Retainability testing by end users passed all acceptance criteria.

4.9 CONCLUSIONS

The Proposed Device, TubeClear is substantially equivalent to the Predicate Device, TubeClear.

The Devices have the SAME:

1. Indications for Use.
2. Operating Principle.
3. Materials.
4. Construction.
5. Shelf Life.
6. Packaging.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2012

Actuated Medical, Inc.
% Debora L. Demers, Ph.D.
Director, Quality Assurance and Regulatory Affairs
310 Rolling Ridge Drive
BELLEFONTE PA 16823

Re: K123659
Trade/Device Name: TubeClear™ Model 101
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: November 26, 2012
Received: November 30, 2012

Dear Dr. Demers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 2

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123659

Device Name: TubeClear™ Model 101

Indications for Use Statement

TubeClear™ is indicated for use only and solely in clearing occlusions / clogs in nasogastric (NG) tubes (i.e., tubes that are placed through the nose and reside in the stomach) of adult patients. Clearing Stem Model NG-1036 is indicated for use in nasogastric tubes that are of size 10 – 14 French and have a length of 36 – 42 inches (91 - 108 cm). Clearing Stem Model NG-1043 is indicated for use in nasogastric tubes that are of size 10 – 18 French and have a length of 43 - 50 inches (109 – 127 cm).

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K123659